

REMARKS

Applicants thank Examiner Ariani and her supervisor, Examiner Wityshyn for the courtesies extended to the undersigned during a telephonic interview. The Office Action rejected claims 73-78. By this amendment, Applicants have amended claims 73, 74 and 76 and added new claim 78.

I. Claim Rejections under 35 USC 112

The Office Action rejected claims 74 and 76 under 35 USC 112 suggesting that the use of the trademark Tetronic®1304 made those claims indefinite. Without acquiescing in this rejection, Applicants have amended claims 74 and 76 in a manner that addresses the rejection.

II. Claim Rejections under 35 USC 103

The Office Action rejected claims 73-77 under 35 USC 103 as being unpatentable over Kamien M. (Aust. Fam. Physician. 1999, vol. 28, No. 8, p. 817-828, Abstract) in view of Asgharian et al. (US Patent 6,139,646), and further in view of Hunt et al. (US 5,897,833), and further in view of Rothberg, S. (Science 1967, Vol. 156, p. 90-93). Applicants request reconsideration of this rejection based upon the following discussion.

During the Interview with examiners Ariani and Wityshyn, Applicants explained that the skilled artisan would be unlikely to combine Asgharian et al. with Kamien M. for at least two reasons. First, on a general level, Asgharian et al. is directed to contact lens disinfecting compositions and there is no indication in the prior art that such compositions would be desirable for the removal of human cerumen from an individual's ear canal. Second, the amounts of sodium bicarbonate suggested in Asgharian et al. are likely too low to effectively digest appreciable amounts of human cerumen and the amounts are outside of the range recited in the claims of the present application.

Upon explaining this reasoning during the Interview, Examiner Wityshyn suggested that the second reason sounded compelling and that Applicants should develop this reasoning in their response. As such, Applicants explain this reasoning in greater detail.

The Office Action asserts that Asgharian et al., "...teach sodium bicarbonate in an amount of at least 0.2% (Example 4)." However, a closer look at Example 4 of Asgharian et al. reveals that the formulation of Example 4 is for a tablet that is later diluted to form a contact lens

disinfecting solution. Such a tablet would be unfit for digesting cerumen. Moreover, the purpose of the sodium bicarbonate of that tablet is to act as an effervescing agent that assists dissolution of the tablet when the tablet is dissolved in liquid. Thus, the concentration of sodium bicarbonate in the composition of Asgharian et al. is substantially lower than the concentration asserted by the Office Action.

In particular, the procedure for dissolving the tablet is described at column 15, lines 55-65 of Asgharian et al. The liquid is added to the tablet and, upon dissolution of the tablet, the sodium bicarbonate concentration is approximately 0.007 w/v%. This concentration is substantially below the range recited in Applicants' currently pending claims. Further, this amount of sodium bicarbonate is very unlikely to provide the composition with any sufficient capability to effectively digest human cerumen.

Because Asgharian et al. is directed to the formation of contact lens disinfecting solutions and because of the purpose of the sodium bicarbonate as an effervescing agent in Asgharian et al. and because of the low amounts of sodium bicarbonate employed in Asgharian et al., it is quite unlikely that the skilled artisan would use the teachings of Asgharian et al. in forming a composition for digesting human cerumen. It is even more unlikely that the skilled artisan would be motivated to form a composition having the amounts of sodium bicarbonate and MeTrypsin recited in the claims of the present application. On this basis, Applicants respectfully request reconsideration of the rejection of the present claims.

CONCLUSION

Should the Examiner have any questions regarding this Amendment, please feel free to contact the undersigned attorney at the phone number listed below.

Respectfully submitted,

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